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Patent Application

Attorney Docket No. 3153.00200/PC10761A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Mohamad A. Morsey, et al.

APPLICATION NO.: 09/938,700 Examiner: Jamroz, Margaret E.

FILING DATE: August 24, 2001 Group Art Unit: 1644

TITLE: ANTI-IgE VACCINES

COMMISSIONER OF PATENTS AND TRADEMARKS
WASHINGTON, D.C. 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENTRECEIVED
JUN 19 2002
TECH CENTER 1600/2900

This Response is being submitted in response to an Office Action dated April 5, 2002, paper number 8. Applicants hereby Petition for an Extension of Time of one month to respond to the Outstanding Office Action. Enclosed herewith is a check in the amount of \$110.00 in payment therefor.

Restriction to one of the following groups is required under 35 U.S.C. § 121:

1. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 1, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

2. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 2, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

3. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 3, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

4. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 4, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

5. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 5, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class

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424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

6. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 6, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

7. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 7, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

8. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 8, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

9. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 9, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

10. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 10, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

11. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 11, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

12. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 12, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

13. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 13, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class 424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

14. Claims 1-2, 7-13, and 39-41, drawn to an isolated antigen peptide comprising SEQ ID NO: 14, a fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 530, subclass 324, Class

424, subclasses 134.1, 185.1, and 192.1, and Class 435, subclass 810, respectively.

15. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 15 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

16. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 16 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

17. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 17 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

18. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 18 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

19. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 19 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

20. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 20 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

21. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 21 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

22. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 22 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

23. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 23 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a

kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

24. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 24 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

25. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 25 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

26. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 26 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

27. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 27 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

28. Claims 3-6, 14-18, 30-31, and 41, drawn to an isolated polynucleotide sequence comprising SEQ ID NO: 28 encoding an antigenic peptide or fusion protein thereof, a pharmaceutical composition thereof, and a kit; classified in Class 536, subclass 23.1, and Class 514, subclass 44, respectively.

29. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 1; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

30. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 2; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

31. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 3; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

32. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 4; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

33. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic

peptide, or a fusion protein of SEQ ID NO: 5; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

34. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 6; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

35. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 7; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

36. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 8; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

37. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 9; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

38. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 10; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

39. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 11; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

40. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 12; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

41. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 13; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

42. Claims 19-22 and 29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering an antigenic peptide, or a fusion protein of SEQ ID NO: 14; classified in Class 424, subclasses 134.1, 185.1, and 192.1.

43. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 15 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

44. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising

SEQ ID NO: 16 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

45. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 17 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

46. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 18 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

47. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 19 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

48. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 20 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

49. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 21 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

50. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 22 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

51. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 23 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

52. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 24 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

53. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 25 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

54. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 26 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

55. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising

SEQ ID NO: 27 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

56. Claims 23-29, drawn to a method of treating or preventing an IgE mediated allergic disorder comprising administering a nucleic acid comprising SEQ ID NO: 28 encoding an antigenic peptide, or a fusion protein; classified in Class 514, subclass 44.

57. Claims 32 and 34-38, drawn to a method of evaluating the effect of anti-IgE vaccines in dogs comprising administering to the dogs an allergen to induce hypersensitivity followed by challenge with allergen; classified in Class 424, subclass 275.1.

58. Claims 33-38, drawn to a method of inducing high levels of IgE and clinical signs of hypersensitivity in dogs comprising administering to the dogs an allergen and ricin to induce hypersensitivity followed by challenge with allergen; classified in Class 424, subclass 275.1.

Applicants provisionally elect Group 4, claims 1-2, 7-13, and 39-41, for prosecution purposes, with traverse. Applicants hereby conditionally withdraw claims 3-6 and 14-38 from prosecution, without prejudice, and request reconsideration of the restriction requirement.

Applicants traverse the restriction requirement based on the following grounds. It is respectfully submitted that the restriction requirement practice was established to promote efficiency of prosecution in the United States Patent Office. All groups of the claims relate to an antigenic peptide and uses thereof. It is a well-accepted practice in the United States Patent Office to claim a peptide, a related fusion protein, an isolated polynucleotide sequence encoding the peptide, a host cell containing the isolated polynucleotide sequence encoding the peptide, a pharmaceutical composition containing the peptide, a kit containing the peptide, a method of making the peptide, and a method of treatment utilizing the peptide in the same application and without restriction. Accordingly, Applicants believe that it is entirely reasonable, and would not present an undue burden on the Patent Office, for the claims of all the groups to be kept together in the instant application. There is sufficient homology among the groups, wherein a search of one group with one of the SEQ ID NOs. would result in a search of all SEQ ID NOs. claimed in the instant application. Further, the claims of various groups are classified in the exact same class (e.g., groups 1-14 for claims 1-2, 7-13, and 39-41, are all classified under classes 530, 424, and 435). Since there is a great amount of cross-classification among the subclasses of this class, it is respectfully submitted that examination of all of these groups of claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice. Hence, it is respectfully requested that the restriction should not be required and that Applicants

have traversed the restriction requirement. As stated above, however, Applicants have provisionally elected the claims of Group 4 and provisionally withdraw claims 3-6 and 14-38, without prejudice, pending reconsideration of the restriction requirement.

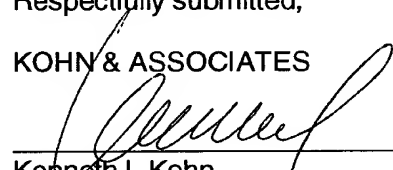
The Office Action also states that Applicants are further required under 35 U.S.C. § 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added. Since claims 1-2, 7-13 and 39-41 of Group 4 have been elected by Applicants, Applicants elect the antigenic peptide pharmaceutical composition that is encoded by SEQ ID NO. 4 with the specific heterologous carrier protein being KLH. Applicants elect the above species without traverse.

The Application is now in condition for allowance, which allowance is respectfully solicited.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES



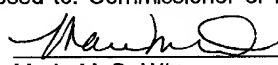
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Dated: June 5, 2002

CERTIFICATE OF MAILING

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I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231.



Marie M. DeWitt